

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

KFX MEDICAL CORPORATION, a Delaware corporation,) Case no. 11cv1698 DMS (BLM)
Plaintiff and Counterdefendant,) OPENING EXPERT REPORT OF JONATHAN B. TICKER, MD.
v.)
ARTHREX, INCORPORATED, a Delaware corporation,)
Defendant and Counterclaimant.)

structure that can be stretched between two or more anchors, and includes, without limitation, traditional suture material, single or multiple stranded threads, or a mesh structure.” *Id.* at 3–4. FiberTape meets this definition of suture.

83. Furthermore, it is my opinion that the common understanding of “suture” also would include FiberTape. Much like shoelaces, both flat and round versions are suture. The portion of the 510(k) summary for FiberTape, submitted by Arthrex and available at the FDA website, asserts that FiberTape is to be classified as “suture, non-absorbable, synthetic, polyester,” and calls it variously the “Arthrex FiberTape™ Family suture products,” and “Arthrex suture tape,” as well as saying explicitly that “Arthrex FiberTape™ Family consists is (sic) a ribbon-like suture.” Available online at http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032245.pdf (last accessed February 20, 2013) KFX0041604-KFX0041607. As FiberTape consists of a piece of #2 FiberWire suture with flat overbraid, it must by necessity be suture. Dreyfuss Deposition on September 16, 2005 in *DePuy Mitek, Inc. v. Arthrex, Inc.*, ARTH_0880321-ARTH_0880450 at p.108-109. Mr. Benavitz also stated in his deposition that TigerTape and FiberTape are both brands of suture marketed by Arthrex. Benavitz Dep. 74:5-16, Nov. 28, 2012.

E. Arthrex Induced Infringement of the ‘311, ‘942 and ‘969 patents

84. I understand that a party who induces infringement by another is itself liable for infringement. I understand that, according to the standard set forth in the AIPLA Model Patent Jury Instructions (©2012), in order for Arthrex to be liable for induced infringement of the asserted patents, KFx must establish that it is more likely than not that: 1) someone infringed at least one patent claim from each of the asserted patents; 2) Arthrex must have aided, instructed, or otherwise acted with the intent to cause acts by another that would constitute direct infringement; 3) Arthrex must have known of the patent, or shown willful blindness to the existence of the patents; and 4) Arthrex knew or should have known that its actions would lead to actual infringement of at least one claim of the asserted patents. I understand that intent to cause the acts that constitute direct infringement may be demonstrated by evidence of active

steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use.

85. I understand that direct infringement of a method claim requires that every requirement of the asserted claim is included in the method performed.

1. **The patents have been directly infringed**

a. **SpeedBridge™ Rotator Cuff Repair**

86. I have reviewed video recordings of several SpeedBridge procedures performed on live and cadaver shoulders which are currently, as of February 2, 2013, posted on Arthrex's website and easily accessible to surgeons. These include one entitled "Arthroscopic SpeedBridge™ Double Row Rotator Cuff Repair," ("Millett"), which was confirmed by Mr. Sodeika, the SpeedBridge™ product manager for Arthrex, to have been performed and taped in 2011, *see* Sodeika Dep. 213:15–214:6, Dec. 3, 2012; *see also* Ex. 99, long after the '311 patent issued. The method performed in this video demonstrates literal infringement of Claims 1, 5, 6, 7, 11, 12, 14, 15, 16, 17, 18, 19, 20, 23, 24, 25, 28, 29, and 30 of the '311 Patent, Claims 1, 2, 3, 4, 5, 6, 7, 11, 12, 13, 14, 15, 16, 17, 18, and 19 of the '942 Patent and Claims 1, 2, 3, 4, 13, 14, 15, 16, and 17 of the '969 patent.

87. Three other videos entitled "Rotator Cuff Repair utilizing ArthroFlex™ Augmentation" dated May 16, 2012, ("Millett Augmented"), "SpeedBridge™ Rotator Cuff Repair with Medial Double Pulley" dated April 12, 2011, ("Burkhart 1"), and "SpeedBridge™ Rotator Cuff Repair Cadaver Demonstration" dated July 21, 2010, ("Burkhart 2"), are also currently promoted on the Arthrex web site, and show procedures in which the methods performed directly infringe the above-referenced claims of the patents.

b. **SutureBridge™ Rotator Cuff Repair**

88. I have reviewed multiple videos produced by Arthrex and on their website of surgeons performing SutureBridge Rotator Cuff Repairs on patients and cadavers. In my opinion, the video of Dr. Burkhart entitled "PASTA SutureBridge" and dated April 12, 2011, ("Burkhart PASTA"), shows a rotator cuff repair in which every requirement of at least the

following claims are included in the method performed: Claims 1, 5, 6, 7, 11, 12, 14, 15, 16, 17, 18, 19, 20, 23, 24, 25, 28, 29, and 30 of the '311 Patent, Claims 1, 2, 3, 4, 5, 6, 7, 11, 12, 13, 14, 15, 16, 17, 18, and 19 of the '942 Patent and Claims 1, 2, 3, 4, 13, 14, 15, 16, and 17 of the '969 patent. The video entitled "SutureBridge® Rotator Cuff Repair Featuring the PushLock® Anchor" dated January, 2006 (ElAttrache video), shows methods of rotator cuff repair in which every requirement of at least the following claims are included in the method performed: Claims 1, 5, 6, 7, 11, 12, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 28, 29, and 30 of the '311 Patent, Claims 1, 2, 3, 4, 5, 6, 9, 10, 11, 12, 13, 15, 16, 17, 18, and 19 of the '942 Patent and Claims 1, 3, 4, 5, 6, 7, 14, 15, and 16 of the '969 patent. It is my opinion that surgeons have performed and continue to perform SutureBridge rotator cuff repairs in a similarly infringing manner, as promoted by Arthrex.

89. It is my opinion that these and other surgeons performing SpeedBridge and SutureBridge repairs as taught in these videos and the various Arthrex marketing materials and hands on demonstrations perform them in a similarly infringing manner. Mr. Benavitz wrote in a 2007 email that Arthrex estimated that more than 7500 SutureBridge procedures were being done monthly. Ex. 71 at 1. By early 2010, he estimated that 140,500 SutureBridge and SpeedBridge procedures were being performed annually. Ex. 33 at 1. There is no reason to believe that the thousands of SpeedBridge and SutureBridge procedures performed monthly are being performed any differently than the way which Arthrex demonstrates to its representatives and surgeon customers in its videos, animations, and techniques.

2. Arthrex has actively and knowingly aided and abetted that direct infringement

a. Arthrex actually intended to cause the direct infringement

90. Based on my review of Arthrex's website, materials produced by Arthrex, and my experience as a surgeon, it is my opinion that Arthrex has actively and knowingly aided and abetted the direct infringement of the '311, '942, and '969 patents. Arthrex's website contains technique guides, animations, and multiple surgical videos, including the seven referenced

above, which demonstrate for surgeons visually and verbally how to perform rotator cuff repairs in manners which infringe the asserted claims. Arthrex trains sales representatives to teach surgeons, including, but not limited to, at National and Regional Sales Meetings, new representative training, in technique guides, brochures, and with white papers. Furthermore, Arthrex provides Directions for Use for the individual products utilized in these procedures, has run multiple advertisements for the procedures. Arthrex has trained representatives to demonstrate to surgeons how to perform the accused techniques. Surgeons are taught by Arthrex employees and consultant surgeons at Arthrex laboratory sites and at meetings to perform rotator cuff repairs in an infringing manner. All of these actions constitute active steps taken by Arthrex, or on behalf of Arthrex with Arthrex's knowledge and approval, to encourage direct infringement.

91. Based on my clinical experience, surgeons learning a procedure through technique guides, sawbones or cadaver hands-on practice, and/or by watching video or animation demonstrations will perform the techniques as they have been taught. Arthrex appears in its documents to share this opinion. Mr. Reinhold Schmieding asked Dr. ElAttrache to provide feedback on the SutureBridge surgical technique guide on January 6, 2006, stating that “[s]urgeons are beginning to do Suture Bridge without a technique reference, which is asking for disaster.” Ex. 123. Mr. Benavitz testified in his 30(b)(6) deposition that it is his expectation that doctors will go to the website to learn about how to perform these procedures from the materials posted, including brochures, presentations, surgical technique animations, surgical technique guides, surgical technique videos, and white papers. Benavitz Dep. 67:4–69:9, Nov. 28, 2012.

b. Arthrex was aware of the ‘311, ‘942, and ‘969 patents

92. Based on my review of Arthrex's documents, it is clear that Arthrex was aware of the ‘311, ‘942, and ‘969 patents. At least as early as August 11, 2006, Mr. John Schmieding, Arthrex's counsel, and Mr. Stephen Soffen, outside patent counsel, were aware of the KFx Suture Cross technique. Ex. 185. At least as early as September 12, 2006, Mr. John

Schmieding and Mr. Stephen Soffen were aware of the KFx application which ultimately issued as the ‘311 patent. See Ex. 187. Emails from August 2009 between John Schmieding and outside patent counsel indicate that Arthrex was aware of the ‘311 patent claims a month before the patent issued. Ex. 195. Mr. Reinhold Schmieding was notified that the patent was about to issue via email chain in August, 2009. Ex. 196. Mr. Dreyfuss, the Arthrex engineer, Mr. Benavitz, the manager of the shoulder group, and Mr. Sodeika, the SutureBridge product manager, according to emails from September 10, 2009, entitled “oh, boy,” were aware of the ‘311 patent claims, reproduced in that email chain. Further, Mr. Dreyfuss expressed a belief that dependent claims 3 and 4, which are not asserted by KFx in this action, were not infringed by Arthrex’s accused methods. Exs. 62 and 146. Because infringement of a patent occurs if any one claim is infringed, the reference to a couple of dependent claims as not infringed suggests the author recognized the infringement of the other claims. As the ‘942 and ‘969 patents issued after this litigation had been initiated, it would be unreasonable to believe that Arthrex was unaware of either patent. Furthermore, both patents were added to the action shortly after the January 24, 2012 issuance of the ‘942 patent and February 8, 2012 issuance of the ‘969 patent. At least Mr. Stewart, Mr. Maas, head of Regulatory, Mr. Sodeika, Mr. Dreyfuss, Arthrex’s legal department (Mr. Price), and Mr. Benavitz knew of the ‘942 issuance by January 24, 2012. See, e.g., ARTH_0148752–ARTH_0148753; ARTH_0148770; ARTH_0148780.

c. **Arthrex knew or should have known that its actions would lead to actual infringement**

93. In my opinion, based on my experience and based on Arthrex’s website and internal documents, Arthrex must have known that performance of the accused techniques would be infringing on the KFx ‘311, ‘942, and ‘969 patents. The techniques, videos, and animations which Arthrex provided and continues to provide to instruct surgeons clearly perform every step in the asserted claims of the ‘311, ‘942, and ‘969 patents. As discussed above, Arthrex would anticipate that surgeons, using these and other Arthrex provided resources, would perform the procedures as they had been taught.

94. For example, as above, it is reasonable to infer from Mr. Dreyfuss' and Mr. Benavitz's emails that they believed that claims other than 3 and 4 of the '311 patent were infringed by Arthrex's techniques. *See* Exs. 62 and 146. Additionally, Mr. Dreyfuss reached out at least once in September, 2009, to try to find evidence that techniques had been performed before the patent's priority dates, because he saw a similarity between SutureBridge and at least Claim 1 of the '311 patent. Dreyfuss Individual Dep. 98:17–111:5, Dec. 5, 2012; *see also*, Ex. 147. Arthrex's patent counsel, before he realized that KFx had filed the '311 application more than a year before Arthrex filed their provisional application based on the SutureBridge, believed that the KFx method was so similar to Arthrex's SutureBridge technique that it was infringing and planned to draft claims accordingly. Ex. 185.

F. Arthrex has contributed to the infringement of the '311, '942, and'969 patents

95. It is my understanding that someone who contributes to another's infringement is liable for infringement. It is my understanding that, according to the AIPLA Model Patent Jury Instructions (©2012), to establish contributory infringement, KFx must prove that it is more likely than not that Arthrex had knowledge of the asserted patents and that 1) someone has directly infringed the asserted patents; 2) Arthrex sold, offered for sale, or imported within the United States an apparatus for use in the infringing method; 3) the apparatus is not a staple article or commodity of commerce capable of substantial non-infringing use; 4) the apparatus constitutes a material part of the patented invention; and 5) Arthrex knew that the component was especially made or adapted for use in an infringing method.

1. The '311, '942, and '969 patents have been directly infringed

96. As explained, *supra*, it is my opinion that Drs. Millett, Burkhart, ElAttrache, Tibone, and other surgeons performing SpeedBridge and SutureBridge repairs as taught in these videos and the various Arthrex marketing materials perform them in a similarly infringing manner. There is no reason to believe that the SpeedBridge and SutureBridge procedures being referred to in these documents are being performed any differently than how Arthrex demonstrates to its representatives and surgeon customers in its videos, animations, and

techniques.

2. Arthrex offered for sale and sold kits for use in the infringing procedures

97. Arthrex has offered for sale and sold kits specifically designed for and labeled with the infringing procedure; namely, Arthrex®SutureBridge® Implant Set kits and Arthrex®SpeedBridge™ Implant Set kits.

98. The SutureBridge Implant System (AR-1926SBS) consists of two PushLock anchors and two Corkscrews. These kits were first promoted for use in infringing SutureBridge procedures in March, 2006. Arthrex also applied for and was granted a trademark, Registration Number 3696486, for “Arthrex SutureBridge,” described as kits consisting primarily of a suture and a suture anchor for surgery. See <http://tess2.uspto.gov/bin/showfield?f=doc&state=4008:pz2liz.2.1> KFX0041649-KFX0041650.

99. At least four SpeedBridge kits are currently offered for sale on the Arthrex website, including SpeedBridge Implant System with Bio-SwiveLock (AR-2600SBS-2) and SpeedBridge Implant System with Bio-SwiveLock SP (AR-2600SBS-3), both introduced in February, 2009, and the SpeedBridge Implant System with BioComposite SwiveLock (AR-2600SBS-4), and SpeedBridge Implant System with BioComposite SwiveLock SP (AR-2600SBS-5), both introduced in October, 2010. The SpeedBridge kits consist of four SwiveLock anchors and two pieces of FiberTape, either preloaded or supplied with the system. All but the Bio-SwiveLock SP system also contain a disposable punch. See Ex. 26; see also www.arthrex.com/products/AR-2600SBS-5, www.arthrex.com/products/AR-2600SBS-4, www.arthrex.com/products/AR-2600SBS-3, and www.arthrex.com/products/AR-2600SBS-2. Arthrex only promotes on its website the SpeedBridge Implant Systems for use in the infringing SpeedBridge procedures. See, e.g., <http://www.arthrex.com/shoulder/speedbridge-implant-system>.

100.

3. The SutureBridge and SpeedBridge kits are not staple articles or commodities of commerce capable of substantial non-infringing use

101. I understand that a “staple article or commodity of commerce capable of substantial non-infringing use” is something that has uses other than in the patented method, and those other uses are not occasional, farfetched, impractical, experimental, or hypothetical. AIPLA Model Patent Jury Instructions (©2012). Arthrex offers all of the components in each kit for sale individually. As described above, these kits were specifically created for use in SpeedBridge and SutureBridge procedures. They were exclusively marketed and promoted for such on the Arthrex website. A surgeon would, for non-infringing uses, open individual anchors suitable for the construct he or she was creating. For example, 3.5 PushLock anchors are also used for labral repairs in the shoulder. However, typically, 3-4 PushLock anchors would be used and there would be no reason to use a Corkscrew anchor. Opening a SutureBridge kit with two Corkscrews and only two PushLocks would require separately opening another PushLock and wasting the two Corkscrews. This would incur substantial extra costs over opening the PushLocks separately. Furthermore, the bone of the labrum is hard enough to frequently require drilling, and no drill bit was provided in the kits, so a separate drill would still have to be opened and the punch discarded. For SwiveLock anchors, four anchors are too many for substantial non-infringing use. There is no reason to believe that the kits would have been used for procedures other than the infringing SpeedBridge and SutureBridge rotator cuff repair procedures.

4. The SpeedBridge and SutureBridge kits constitute a material part of the patented invention

102. The SpeedBridge and SutureBridge kits contain all four anchors, plus suture, implanted while performing a standard SpeedBridge or SutureBridge repair as taught by Arthrex in its videos, animations, technique guides, and other marketing materials. These kits provide all implants necessary to perform the accused SutureBridge and SpeedBridge procedures in a manner which infringes the asserted claims of the ‘311, ‘942, and ‘969 patents.

5. Arthrex knew that the apparatus was especially made for use in an infringing method

PROOF OF SERVICE

I am a citizen of the United States of America and I am employed in San Diego, California. I am over the age of 18 and not a party to the within action. My business address is 12790 El Camino Real, San Diego, California. On February 21, 2013, I served the within **OPENING EXPERT REPORT OF JONATHAN B. TICKER, MD** on the parties or their counsel shown below as follows:

VIA EMAIL LINKING TO FTP SITE

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I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on February 21, 2013 at San Diego, California.



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